Noninvasive Biosensor Algorithms for Continuous Metabolic Rate Determination

Completed Technology Project (2007 - 2010)

Project Introduction

NASA is designing new spacesuits to meet the needs of future space exploration. Real-time measurement of metabolic rate during astronaut activity is a key function of the biosensor suite which is planned for the new spacesuit. This project is developing novel near infrared spectroscopic (NIRS) algorithms and sensors for real-time assessment of metabolic rate (measured as the rate of oxygen consumption, VO2). This capability is intended to be incorporated into a smart system advising astronauts on their use of consumables during extravehicular activity (EVA). The specific aims of this project include the development of algorithms to calculate VO2 from NIRS spectra and validation of the algorithms during exercise in two different ground-based protocols which simulate plasma volume reduction during spaceflight. An additional aim of this project is to support the EVA suit testing program by developing small, lightweight and robust sensors which can be used within the spacesuit to evaluate metabolic cost of the suit itself, on individual muscles.

Over the last year we have made significant progress in developing the components of the algorithm to calculate VO2 from NIR spectra. We have completed the initial algorithm to estimate stroke volume and made advancements in improving the accuracy of our hematocrit calculation. We have further optimized our measurement of muscle oxygen saturation and demonstrated its high degree of accuracy under a number of potential confounding factors. Most important for space application, we demonstrated accuracy under conditions that simulate factors that occur during fluid shifts, i.e., variation in blood and water fraction, as well as changes in blood vessel size.

We completed data collection for a study of pharmacologically induced hypovolemia, one of the validation studies we will use to assess performance of our VO2 algorithms. Initial data analysis showed that noninvasively determined NIRS parameters, muscle oxygen saturation, and hydrogen ion threshold were not different between the hypovolemia and normovolemia exercise sessions. This result is in agreement with the finding that lactate at peak exercise was not different between the 2 groups.

With synergistic funds from the US Army Medical Research Command we continued to develop the solid state sensor and software to support it. The first systems were delivered to Johnson Space Center (JSC) for testing in the Exercise Physiology lab. Hardware and software usability was greatly improved over the fiber optic system according to the users.

This project has produced a prototype wearable sensor that terrestrial doctors and their patients can use to track and optimize exercise in the management of health and fitness, as well as during related applications in the care of critically ill patients. A company has been formed to commercialize the sensor. The company is on target to submit a 510(k) application to the FDA (Food and

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Table of Contents

Drug Administration) in early 2011.

Anticipated Benefits

This work will have direct Earth-based application. The fitness and exercise applications we are developing can be used to assist in the training and evaluation of elite and recreational athletes. This direct application of interest to NASA for assessing fitness in space may be useful to assess success of physical therapy in rehabilitating patients with muscle injury or atrophy.

The sensor, which also is of tremendous interest to the Army, will have application in emergency response vehicles, emergency rooms, and hospitals. Pre-hospital applications include assessing the severity of shock and triaging multiple casualties, as well as providing a sensor for a smart medical system to guide resuscitation from hemorrhage. In the Intensive Care Unit (ICU) we expect that this monitor will find application in helping provide early identification of patients with hemodynamic instability before they go into shock.

We are partnering with the Armed Forces Research Institute of Medical Science (AFRIMS) in Bangkok, Thailand to study the application of our sensor for the early identification of shock in children with Dengue hemorrhagic fever. This study is funded by Telemedicine & Advanced Technology Research Center (TATRC). We have received IRB (institutional review board) approval and traveled to Bangkok to train the research nurses. Patient enrollment will begin in September.

The company formed to commercialize the sensor has received a Phase II STTR (Small Business Technology Transfer) grant from the US Army. This effort is focused on obtaining FDA clearance through the 510(k) mechanism, to market the sensor in the US. The company is on track to submit this application in early 2011.

Organizational Responsibility

Responsible Mission Directorate:

Space Operations Mission Directorate (SOMD)

Lead Organization:

National Space Biomedical Research Institute (NSBRI)

Responsible Program:

Human Spaceflight Capabilities

Project Management

Program Director:

David K Baumann

Principal Investigator:

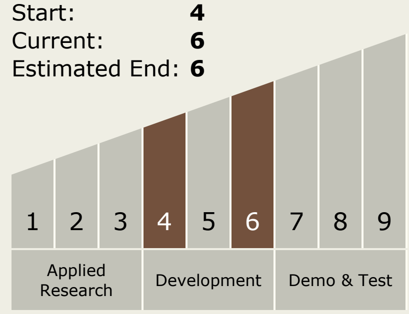
Babs R Soller

Co-Investigator:

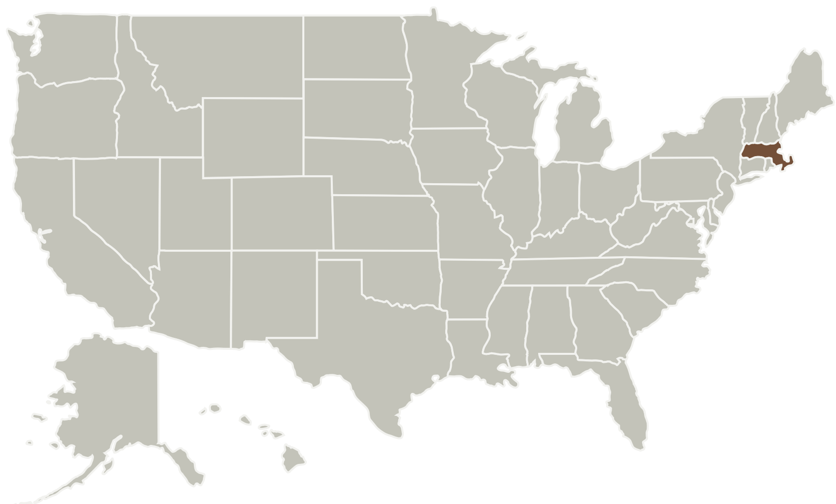
Stuart M Lee

Technology Maturity (TRL)

Start: **4**
Current: **6**
Estimated End: **6**



Primary U.S. Work Locations and Key Partners



Organizations Performing Work	Role	Type	Location
National Space Biomedical Research Institute(NSBRI)	Lead Organization	Industry	Houston, Texas
Reflectance Medical Inc.	Supporting Organization	Industry Women-Owned Small Business (WOSB)	
Wyle Integrated Science and Engineering Group	Supporting Organization	Industry	

Primary U.S. Work Locations
Massachusetts

Technology Areas

Primary:

- TX06 Human Health, Life Support, and Habitation Systems
  - └ TX06.3 Human Health and Performance
    - └ TX06.3.4 Contact-less / Wearable Human Health and Performance Monitoring

Target Destinations

The Moon, Mars

Project Transitions

October 2007: Project Start

September 2010: Closed out

Closeout Summary: Our collaborators in the JSC Cardiovascular lab implemented a technique to determine stroke volume during exercise using ultrasound imaging. Data collection using this technique has been completed for 31 subjects.Spectral data collection has been completed on 6 subjects, both pre- and post-bed rest. Additionally, spectral data collection has bee n completed on 5 subjects in the hypovolemia study. Data review and analysis is underway.Initial data review indicated tha t we needed to gain a better understanding of the impact of fluid shifts on our NIRS measurements. We conducted a stand test to determine the effect of postural changes on our NIRS measurements, including an independent assessment of blood volume using regional bioimpedance measurements. We learned in this study that it takes 15 min after a transition from st anding to supine for the blood volume to normalize across all anatomical sites. We took advantage of this information in a s tudy at UMass (University of Massachusetts) to investigate the sensor's ability to measure SmO2 on different muscles throu gh various fat thicknesses. After 15 min of supine rest to allow blood to normalize across the body we demonstrated on 6 s ubjects that SmO2 measurements were equal, despite the choice of muscle used for the measurement (shoulder, calf, uppe r thigh, or lower thigh). This study included fat thickness that ranged from 5-19 mm.We have received synergistic funding f rom non-NASA sources to develop a solid state, low profile sensor that can be worn in a space suit for determining metaboli c rate. During this year we completed development of the prototype and demonstrated that it was equivalent to our fiber o ptic model in the measurement of muscle oxygen saturation and pH. With additional National Space Biomedical Research In stitute (NSBRI) support we also developed the technology to run the sensor off a battery pack and augmented our system automation to include on-the-fly error checking and correction. The requirements for the additional automation features we re the result of feedback from our NASA collaborators, based upon their previous experience using our original fiber optic sy stem. In exercise studies we found that the optical signal can degrade during certain exercise periods. The new sensor is ab le to detect these problems and correct them within a few seconds, so no data is lost.SUPPLEMENTAL INFORMATION FOR O ctober 2009-September 2010 (submitted November 2010):- Over the last twelve months spectral data collection has been completed on 15 subjects, both pre- and post-bed rest. The spectral data collected at JSC is uploaded to a shared server. Al l spectra are examined for spectral integrity. Spectral parameters SvO2, Hb, and SaO2 are then averaged over 30 sec inter vals and matched to the VO2 data determined with the metabolic cart. When the stroke volume algorithm is completed, VO 2 will be calculated from the spectra and compared to the gold standard measurement.- Data collection for the hypovolemia study was completed. A total of 12 subjects (8 male and 4 female) completed the study. NIRS data was processed the sam e way for the hypovolemia study as is described above for the bed rest studies. Additionally, the hydrogen ion threshold wa s calculated from the spectra for both the normovolemic and hypovolemic exercise sessions. There were no differences obs erved between normo and hypovolemic exercises in either H+ threshold or the values of SmO2 through the exercise stage s. This is consistent with the observation of similar blood lactate at peak exercise.- Data collected from 10 healthy subjects were used to determine an initial model for stroke volume. This model was used to estimate VO2 for the same subjects. Est imated accuracy in calculating VO2 was not good enough, with larger errors occurring for exercise levels which are greater t han 60% of maximum workload. The source of the error was traced to poor estimation of stroke volume at higher workload s. We continue to work on improving the estimation of stroke volume.- We made significant improvements in the accuracy and reproducibility of our algorithms to calculate muscle oxygen saturation and hemoglobin concentration. A paper describi ng the improvements in the SO2 model and its validation on simulated spectra and high fidelity phantom materials is in pre ss at a biomedical optics journal.- Two solid state sensors were delivered to Johnson Space Center, along with significantly i mproved user interface software. The new user software incorporates many of the comments from JSC users of our earlier system. The new system reduces the calibration time, automatically resets the sensor during periods of low and high blood flow, and allows incorporation of user comments. Users in the JSC Cardiovascular and Exercise Laboratories were trained on the system. The new system and software were well received. Initial studies with the device have begun in the Exercise La b.EDITOR's NOTE (11/9/2010): Principal Investigator (PI) changed affiliation around October 2010 from University of Massa chusetts Medical School to Reflectance Medical Inc. and a new grant number was issued. End date thus changed to 9/30/20 10, per NSBRI, for Noninvasive Biosensor Algorithms for Continuous Metabolic Rate Determination, grant NCC 9-58-SMS 01 301. See PI Soller and project Noninvasive Biosensor Algorithms for Continuous Metabolic Rate Determination--SMS01302 f or subsequent reporting

Stories

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Project Website:

https://taskbook.nasaprs.com